DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127-2601

Telephone: 504-253-4519
FAX: 504-253-4520

June 22, 2001

WARNING LETTER NO. 2001-NOL-31

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Sister Laureen Painter, CEO
Christus Coushatta Health Care Center
1635 Marvel Street
Coushatta, Louisiana 71019

Dear Sister Painter:

We are writing to you because on June 5, 2001, your facility was inspected by a representative of the State of Louisiana, acting on behalf of the U.S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- **Phantom quality control records were missing for at least 4 weeks for unit 1, Lorad Medical Systems Inc.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem has been identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to **correct** the violation noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations; and,
- include sample records that demonstrate proper record keeping procedures, if the findings relate to quality control (Phantom QC, Processor QC).

Please submit your response to:

Rebecca A. Asente, Compliance Officer
U.S. Food and Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127-2601
Telephone: (504) 253-4519

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U. S. Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Stacy G. Marshall at (504) 253-4554.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District Office

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

Jim Potter, Director
Government Relations
c/o American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

June 22, 2001

VIA FEDERAL EXPRESS

Louis C. Mathews III, Owner & President
Louis C. Mathews Seafood
518 Martin Luther King Boulevard
Savannah, GA 31401

Warning Letter
01-ATL-54

Dear Mr. Mathews:

On February 13, 2001, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your plant located at Savannah, Georgia. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh, histamine-susceptible fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The HACCP deviation of concern is as follows:

> You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for scombroid fish, namely mahi mahi, tuna, and wahoo, does not list the critical control point (CCP) of cooler storage for controlling the hazard of histamine formation.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and

the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District